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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,987	10/21/2004	Judith Aronhime	1662/58602	8819
26646 7590 04/11/2007 KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			EXAMINER LAO, MARIALOUISA	
			ART UNIT	PAPER NUMBER
			1621	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/11/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,987	ARONHIME ET AL.	
	Examiner	Art Unit	
	MLouisa Lao, Ph.D.	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-7 and 10-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7 and 10-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 3/5/07 have been fully considered but they are not persuasive.
2. In view of the Applicants' amendment, the **anticipatory part** of the rejections under 35 USC § 102/103 of claims 1-2, 5-7 and 10-26 **is withdrawn**.
3. However, further in light of the Applicants' amendment, the **obviousness part** of the rejections under 35 USC § 102/103 **is maintained**.
4. Examiner acknowledges the Applicants' arguments on the particle size of the lamotrigine particles stated by cited reference US`179. However, as the Applicants have quoted the appropriate lines thereto, it is apparent that the particles of US`179, which have a typical size of <125µm read on the particle size of the instant claims of 50µm. Further, in the last two lines of page 6, bridging to the first three lines of page 7 of the reply, Applicants have stated that the *"input powders to adhere to one another so the resulting granules should be larger than the input powders"* of US`179 column 3, lines 37-44 interpreting the "input powders" as the lamotrigine particles, where US`179 was referring to the "fluidizing powder", see lines 43-44 of column 3 and not the lamotrigine particles *per se*. Applicants in the reply on page 7 2nd¶ further equate the granules, which comprise lamotrigine *and the fluid granulation additives*, to mean as the lamotrigine particles *per se*, which are passed through the granulator with a discriminatory sizing of the resultant granules.

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Hence, in light of the non-persuasiveness of the arguments presented, the rejection (and further in view of Sawyer et al. (US4602017, US'017) under 35 USC § 103 of the claims, as amended is **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 5-7 and 10-15 are rejected under 35 U.S.C. 103(a) as obvious over Hiskett et al. (US5861179, US'179). In col1 lines 13-67, col2 lines 1-67, col3 lines 22-29 and col3 lines 58-60, Hiskett et al. disclose the powder formulations of lamotrigine...with average particle sizes... below 125µm. In col1 lines 5-10, Hiskett et al. teach the pharmaceutical compound lamotrigine, the pharmaceutical formulation of lamotrigine and pharmaceutically acceptable acid addition salts thereof.

US'179 reads on the instant application's claims 5 and 10-15, which recite the pharmaceutical composition of lamotrigine spanning particle sizes of 100 μ m, 50 μ m and 10 μ m as well as solid oral dosage form. See Examples.

US '179 also **reads on** the use of the lamotrigene as recited in the **instant claims 25 and 26**. See column 1, lines 9-13.

Hiskett et al. is silent on a plurality of lamotrigine particles having a specific surface area as recited on the instant claims 1, 2, 6 and 7. However, a compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). Since there is a relationship between particle diameter and specific surface area, reduced particle size inherently leads to increased surface area, an artisan with ordinary skill in the art at the time of the invention would know and is logically motivated to apply known particle size reduction techniques as these are well known optimization steps both in the art and as taught by the prior art with a reasonable expectation that these efforts will attain the desired particle and/or granular size as in the instant claimed application. And the artisan of ordinary skill in the art would know that the reduced size would logically parlay to an increased specific surface area.

It is *prima facie* case obvious to combine the teachings of the '179 patent with the well established relationship between specific surface area and average particle diameter in order to achieve the characteristics of the plurality of lamotrigine particles. Further, one of ordinary skill in the art would have been motivated to optimize the particle size of the lamotrigene particles because the optimization step is considered well in the competence level of an ordinary skilled artisan in the pharmaceutical science, involving merely routine skill in the art. Furthermore, it is within the skill in the art to select optimal parameters, such as amount of ingredients, granular

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size and specific surface area, in a composition in order to achieve a beneficial effect of increased dissolution.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the '179 patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiskett et al. (US5861179, US'179) in view of Sawyer et al. (US4602017, US'017). In col1 lines 13-67, col2 lines 1-67, col3 lines 22-29 and col3 lines 58-60, Hiskett et al. disclose the powder formulations of lamotrigine...with average particle sizes... below 125 μ m. In col1 lines 5-10, Hiskett et al. teach the pharmaceutical compound lamotrigine, the pharmaceutical formulation of lamotrigene and pharmaceutically acceptable acid addition salts thereof in solid form. Sawyer et al. teaches the use of compounds of the general formula (III), which embraces lamotrigine, for the treatment of CNS disorders. Further, US'017 teaches the use of said compounds in pharmaceutical formulations which can be administered in liquid or solid form. See column 3, lines 18-68 through column 4, lines 1-31. It would have been obvious for one skilled in the art to apply the teachings of Sawyer et al. for liquid formulations to the Hiskett et al. solid pharmaceutical formulation of lamotrigine in order to arrive to the claimed liquid oral dosages of claims 16-24.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art is indicative of the level of the art, which show that optimization techniques to achieve desired particle sizes and the pharmaceutical compound - lamotrigine, its pharmaceutical compositions and its use are well known in the art.

THIS ACTION IS MADE FINAL.

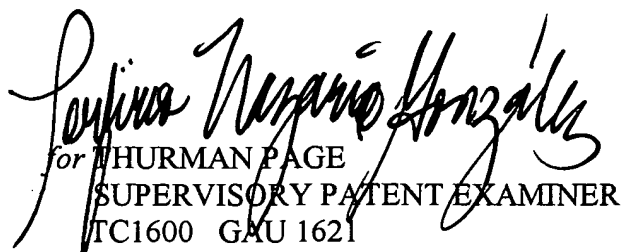
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136 (a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no even, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MLouisa Lao, Ph.D. whose telephone number is 571-272-9930. The examiner can normally be reached on Mondays to Fridays from 8:30am to 5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ml 04042007
MLouisa Lao, Ph.D.
Examiner
Art Unit 1621


for THURMAN PAGE
SUPERVISORY PATENT EXAMINER
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